UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,077	06/23/2003	Stephen Suffin	10701-011	1225

20583 7590 11/30/2005

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,077	SUFFIN, STEPHEN	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 9/8/05 wherein the specification was amended; claims 1-39 and 43-49 were canceled; and claims 40-42 were amended.

Note: Claims 40-42 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENTS

2. The Applicant's arguments filed 9/8/05 to the rejection of claims 40-45 made by the Examiner under 35 USC 103, 112, and/or double patenting have been fully considered and deemed persuasive-in-part for the reasons set forth below.

112 Rejections

The 112 rejections are WITHDRAWN because Applicant has amended the claims to overcome the rejections.

Double Patenting Rejections

The statutory double patenting rejection has been WITHDRAWN because Applicant has amended the claims. However, claim 40 is now rejectable under obviousness type double patenting as set forth below.

103 Rejections

The 103 rejections are WITHDRAWN because Applicant has amended the claims to overcome the rejection.

NEW GROUNDS OF REJECTION

Double Patenting Rejection

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent

possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claim 40 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 49 of copending Application No. 10/193,735. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to determining drug effect on a subject wherein a drug is administered to a subject and post administration, neurophysiologic information is obtained and analyzed. The claims differ in that those of 10/193,735 are directed to determining the effect on the central nervous system wherein the instant invention is not limited to drug effect on

the central nervous system. Hence, a skilled practitioner in the art would recognize that the claims of the instant invention encompass those of 10/193,735.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Note: It is duly noted in Applicant's response filed 9/8/05 that Applicant has requested that the double patenting rejection be withdrawn because claim 49 of 10/193,735 will be canceled upon receipt of the first office action. The double patenting rejection with be withdrawn once claim 49 has been canceled.

112 Rejections

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because they do not clearly set forth Applicant's claimed invention. In particular, the phrase 'determining an electrotherapeutic drug effect' is ambiguous because it is unclear what effect Applicant is attempting to determining. Is it an increase or decrease in localization of the drug? Is it an inhibition of a pathway, etc. Hence, it is unclear what effect is being sought. Also, the phrase 'at least one multivariate out measurement' is confusing because the multivariate out measurements are quantitative output measurements collected form combinations of univariate neurophysiologic measurements obtained from various locations in the brain. However, it is unclear which combinations and neurophysiologic measurements are being obtained with the instant invention. In addition, Applicant use of the phrase 'neurophysiologic information' is confusing because

neurophysiologic information is the information obtained from the measurement of electronic or chemical impulses caused by brain function using techniques such as EEG/QEEG, MNRI, fMRI, PET, SPECT, etc. Thus, the claim as written neither sets forth the technique being used to obtain the neurophysiologic information or what information is being sought. As a result, one cannot readily ascertain what is being claimed. Also, the phrase 'abnormal electroencephalogram' is vague and indefinite because it is unclear how Applicant is defining 'abnormal'. Furthermore, the phrase 'comparing said abnormal information with said follow-up information under conditions such that...changed' is ambiguous because it is unclear what conditions Applicant is referring to. In particular, it is unclear whether the conditions that Applicant is referring to are the same, similar, or totally different from those used to obtain the abnormal information.

103 Rejection

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (US Patent No. 4,735,246).

Freeman disclose a method and apparatus for producing enhanced EEG or MEG information related to brain activity in a subject. Control and test traces are recorded before and during an interval in which the brain activity is occurring and decomposed into a series of functions which may be analytic components (see entire documents, especially, abstract; column 2, lines 20-34). The signals are used to provide information about abnormal disease

state and/or information about the distribution and localization of brain activity which is related to a behavioral event (column 4, lines 36-41). Possible applications for the method disclosed by Freeman include diagnosing neurological disorders or a method of using the signal to investigate the effects of drugs on certain mental states . Studies of this type enable one to establish drug dosage and duration parameters and/or pharmacokinetic or drug effects on certain behavioral activity (column 13, lines 15-68; column 14, lines 1-8). Furthermore, brain mapping allows one to determine the localizing and spatial distribution of brain activity associated with certain brain functions (column 14, lines 10-36). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Freeman and generate a method of determining a drug effect by (a) obtaining an abnormal EEG prior to the administering of a drug; (b) administer a drug and obtain neurophysiologic information; and (c) comparing the data prior to administering the drug with that obtained after administering the drug because (1) both Freeman and Applicant disclose inventions wherein control and test traces (EEG) are recorded before and during an interval in which brain activity is occurring. (2) Both Applicant and Freeman disclose inventions that are used for diagnosing neurological disorders wherein the method of obtaining the signals may be used to investigate the effects of drugs on certain mental states. (3) Both Applicant and Freeman disclose the use of brain mapping herein information comprising at least one multivarirate outcome measurement is obtained from the subject and compared with data obtained prior to administering the drug.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1618

November 28, 2005